REMARKS

1. Applicants acknowledge that claims 1-31 and 37-55 are under examination in the above-identified application, and claims 32-36 and 56-83 are withdrawn from consideration without waiver or prejudice.

Information Disclosure Statement

2. Applicants submit herein a Supplemental IDS having the correct citation for the Tang, et al. U.S. patent application (U.S. Patent Publication No. 2002/0049303).

Claim rejection – 35 USC § 102/103

3. Claims 1-7, 9-13, 15-18, 21, 37-42, 44-46, 49, 50 and 52-54 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over, Reimann et al. (hereinafter "Reimann").

Applicants have amended claim 1 to specify that the average cell diameter of cells contained in the cryogenic vessel is at least 0.5 μm greater than the average cell diameter of uninfected cells of the same type. Support for this amendment can be found, for example, on pages 6, 15-19, Example 1 and Figures 1, 4 and 5 of the specification as originally filed. Therefore, as the Examiner will appreciate based on the specification and claims as originally filed, no new matter is being added by this amendment.

The Examiner's comments have been carefully considered, and the rejections are respectfully traversed.

Applicant's respectfully disagree with Examiner's statement that the Reimann protocol discloses or suggests in an enabling manner all of the elements of the present invention. To constitute anticipation, all material elements of a claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CAFC 1978). Further, an inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities." Scaltech, Inc. v. Retec/Tetra, LLC, 51 U.S.P.Q.2d 1055, 1059 (Fed. Cir. 1999). Additionally, in order to sustain a finding of anticipation, the disclosure of a prior art reference must be adequate to enable possession of the desired subject matter, and a reference that names or describes such desired subject matter does

not anticipate if the subject matter cannot be produced without undue experimentation. Moreover, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. Elan v. Mayo Foundation, 68 USPQ2d 1373 (Fed.Cir. 2003).

A finding of non-obviousness must be based on a comparison of the claimed invention with the teachings of the prior art. Graham v. John Deere, 148 USPQ 459 (Fed. Cir. 1966).

Reimann's protocol is directed to the cryopreservation of PBMC cells derived from HIV-1 infected individuals for use in very specific immunotyping and in *in vitro* assays of immune function. Specifically, Reimann describes a cryopreservation technique of PBMCs and compares the PBMC cells to specimens of fresh whole blood lymphocytes used in a proliferation assay, fluorescence intensity histograms, as well as observes changes in immunophenotypes during density gradient isolation.

The PBMC cells described in Reimann are a heterogeneous mixture of cells derived from a diverse population of individuals, making them highly variable in their characterization, and thus very distinct and different from host cells susceptible to infection with a particular virus of interest. Consequently, because of the nature of the PBMC cells used in Reimann, Reimann does not provide any descriptive guidance as to the effects of cryopreservation on cells that are used to infect host cells. This is clearly evidenced by Reimann's silence in disclosing the type of criteria and specific characteristics necessary for virally infected cells, such as, for example, cell diameter, as described in the present invention. (See, for example, pages 6, 15-19, Example 1 and Figures 1, 4 and 5 of the specification as originally filed.) Therefore, without the benefit of the disclosure of the present invention, one of ordinary skill in the art would not know from Reimann how to carefully select virally infected cells for a cryogenically protected viral delivery system with little loss of the infective potential of the virus, wherein the average cell diameter of infected cells is at least 0.5 μm.

Furthermore, Reimann's protocol provides no guidance as to the specific characteristics or properties of the admixture, nor does it provide teachings or suggestions of how to deliver infected cells with little loss of the infective potential after preservation. (See, e.g., pages 9,

21-28 and 31 of specification.) Reimann's sole reference to cryopreservation medium is as follows, "PBMC were resuspended in ice-cold fetal bovine serum with 10% dimethyl sulfoxide (DMSO) at 10^7 cells/ml." (Reimann, page 353). In fact, page 358 of Reimann discloses that they were "[u]sing a simplified method of cell isolation and cryopreservation," and never assessed nor observed the particular characteristics in the cell diameter measurements or the admixture, thus further confirming that Reimann does not teach the present invention.

Even if, as the Examiner argues, Reimann did produce PBMCs which where preserved in a delivery system having very specific characteristics and properties to produce stable, viable cells, they were unaware of what was done or how it had been done, and the mere fact that a certain thing may result from a given set of circumstance is not sufficient evidence to support a rejection under 35 U.S.C. §102(b) or in the alternative, under 35 U.S.C. §103(a). SmithKline Beecham Corp. v. Apotex Corp. 74 USPQ2d 1396, 1398 (Fed. Cir. 2005).

Accordingly, the Reimann protocol provides no teaching, suggestion or enabling disclosure that would lead a skilled artisan to an invention of a delivery system for the preparation of virally infected cells having specified characteristics under carefully selected and monitored conditions, such as, for example, having the average cell diameter of cells contained in the cryogenic vessel is at least 0.5 μm greater than the average cell diameter of uninfected cells of the same type, as presently claimed. The rejection is based on unfounded "probabilities or possibilities."

It is respectfully submitted that Reimann does not meet the mandated statutory requirements for sustaining a rejection under 35 USC § 102 or, in the alternative, 35 USC § 103.

Claim rejection – 35 USC § 103(a)

4. Claims 14 and 43 stand rejected under 35 USC § 103(a) as being unpatentable over Reimann as applied to claims 1-7, 9-13, 15-18, 21, 37-42, 44-46, 49, 50 and 52-54 above and, further, in view of Wisneiwski (U.S. Patent No. 6,337,205) (hereinafter the '205 patent).

It is respectfully submitted that a *prima facia* obviousness rejection of claims 14 and 43 has not been properly established. Claims 14 and 43 are written to be dependent on claim 1. Claim 1, as amended, renders moot the §102(b)/103(a) rejection based on Reimann. Dependent claims are non-obvious under §103 if the claim from which they depend is non-obvious. See In re Fine, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Therefore, given that neither Reimann or the '205 patent either implicitly or expressly teach or suggest all of the elements of the present claimed invention, the *prima facia* case of obviousness in the present matter has not been established.

Claim rejection – 35 USC § 103(a)

5. Claims 1-31 and 37-55 stand rejected under 35 USC § 103(a) as being unpatentable over Witt et al. (Journal of Virological Methods, 1987, 17:287-292) (hereinafter "Witt") in view of Freshney (Cryopreservation, Chapter 19) (hereinafter "Freshney"), Invitrogen™ Guide to Baclovirus Expression Vector Systems and Insect Cell Culture Techniques, (hereinafter "Invitrogen"), Kistner et al. (Vaccine, 1998, 16(9/10):960-968) (hereinafter "Kistner"), Clontech Lab. Inc. document (Protocol #PT3494-2, Version #PR19432, published in 2001 (hereinafter "Clonetech"), and Nienhuis (US Patent No. 5,780,447) (hereinafter "the '447 patent").

Applicants respectfully traverse the rejection, particularly in light of the claims as now amended. Despite the fact that some of the individual elements may be disclosed randomly in the above cited references, it is clear that none of these references specifically disclose the percent viability of the infected cells, the average cell diameter of cells contained in the cryogenic vessel as being at least 0.5 μm greater than the average cell diameter of uninfected cells of the same type, as well as the admixture being substantially free of extracellular particles or, that the virally infected cells in a vessel are less than or equal to 250 ml. In fact, the Examiner expressly stated in the May 10th, 2005 Office Action that none of the references cited "recite the percent viability of the infected cells," "detail the volume of the collection receptacle" or disclose the use of the viral delivery system in a "scale-up" manner. (May 10th Office Action, page 10). There are no examples in Witt or any of the other above-cited references of such teachings or suggestions. "An enabling disclosure is not 'tossing out the mere germ of an idea' but the provision of 'reasonable

detail'...in order to enable members of the public to understand and carry out the invention." Genetech, Inc. v. Novo Nordisk A/S, 108F.3d 1361, 1366 (Fed. Cir.) cert. denied 118 S. Ct. 397 (1997).

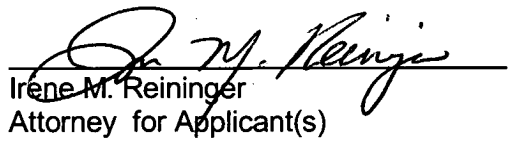
Therefore, even if one were motivated to combine these references, the combination still does not disclose "all the claim limitations." One skilled in the art would not be able to predict, without the benefit of the present specification, such as, for example, charterizing the admixture, assessing the measurement of the cell diameter, or identifying percent viability of infected cells a viral delivery system as disclosed and claimed in the present invention.

Applicants believe that the amendments hereinabove place the Application in condition for immediate allowance. Therefore, entry of the amendments hereinabove, and reconsideration of the Office Action mailed May 10, 2005 are respectfully requested. Such prompt and favorable action is earnestly solicited.

It is also believed that no fee is deemed necessary in connection with the filing of the present amendment. However, if any fees are required, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 16-1445.

Respectfully submitted,

Date: Oct. 14th, 2005



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